

REMARKS

Reconsideration and withdrawal of the objection to Figure 5 and rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1, 3, 49-51, and 65 are amended, claim 68 is canceled; as a result, claims 1-67 and 69 are now pending in this application. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the pending application.

The drawings were objected to under M.P.E.P. § 608.02(g). The Examiner asserts that "Figure 5 should be designated by a legend such as –Prior Art—because only that which is old is illustrated." The rejection does not provide support for this assertion. Consequently, Applicant respectfully traverses the assertion and requests support in the next Official Communication, or withdrawal of the assertion.

The 35 U.S.C. § 102 Rejection

Claims 1, 3, 6-8, 12-13, 22-24, 32-36, 38-42, 44, 49-51, 54, and 65-67 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sherf et al. (U.S. Patent No. 5,744,320). This rejection is respectfully traversed.

Sherf et al. generally disclose dual luminescence reporter assays. It is disclosed that implicit to the concept of an integrated (i.e., sequential-measurement) dual-enzyme reporter assay is the necessity to efficiently quench luminescence from the first reporter enzyme such that the activity of the second luminescent reporter is not inhibited (column 17, lines 33-37). Table 1 in Sherf et al. discloses general quench reagents for firefly luciferase and Table 2 in Sherf et al. discloses general quench reagents for *Renilla* luciferase. The only data disclosing reagents useful to quench one reaction, i.e., reagents that quench a firefly luciferase-mediated reaction, without substantially quenching a subsequent reaction, i.e., without substantially quenching a *Renilla* luciferase reaction, is shown in Tables 4 and 5 (a "selective" quench reagent).

The Examiner is respectfully reminded that the standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its

elements. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q.2d 90 (Fed. Cir. 1986); In re Dillon, 16 U.S.P.Q.2d 1987 (Fed. Cir. 1990).

Sherf et al. do not disclose or suggest a method which employs or kit having a selective quench reagent for a nonbeetle luciferase-mediated luminescence reaction, e.g., a selective quench reagent that quenches a nonbeetle luciferase-mediated luminescence reaction by at least 35-fold. Nor do Sherf et al. teach or suggest a kit having at least one selective quench reagent for an anthozoan luciferase or a kit having a quench-and-activate composition with at least one selective quench reagent that is a nonionic detergent that is not Triton® X-100 or Tween® 20, a substrate analog inhibitor for an anthozoan luciferase, a colored compound, or a combination thereof.

Accordingly, withdrawal of the § 102(b) rejection is respectfully requested.

The 35 U.S.C. § 103 Rejection

Claims 14-15, 43, 47, 52, 55-56, and 68-69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sherf et al. in view of Hawkins et al. (WO 01/96862). This rejection is respectfully traversed.

WO 01/96862 discloses organic reagents, such as organic compounds with a carbon-sulfur or carbon-selenium bond, that reduce autoluminescence in a luminescent reaction, i.e., reagents that reduce release of light from a luminogenic molecule that does not result from enzymatic action on the luminogenic molecule (page 8, lines 5-7).

Thus, WO 01/96862 does not supplement Sherf et al., as WO 01/96862 is concerned with compounds that reduce autoluminescence rather than selective quench reagents for use in dual luminescence assays.

Therefore, withdrawal of the § 103(a) rejection is respectfully requested.

The Nonstatutory Obviousness-Type Double Patenting Rejections

Claims 1, 3, 6-8, 12-13, 22-24, 32-36, 38-42, 44, 49-51, 54, and 65-67 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44 and 54 of U.S. Patent No. 5,744,320. Claims 14-15, 43, 47, 52, 55-56, and 68-69 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 44 and 54 of U.S. Patent No. 5,744,320 in view of Hawkins et al. These rejections are respectfully traversed.

Claim 44 of the '320 patent is directed to a method of assaying enzyme-mediated luminescence reactions comprising initiating a *Renilla reniformis* luciferase-mediated luminescence reaction then quantifying luminescence energy produced by the luminescence reaction, then introducing a quench-and-activate composition that is capable of selectively quenching the *Renilla reniformis* luciferase-mediated luminescence reaction and simultaneously initiating a *Photinus pyralis* luciferase-mediated luminescence reaction, and quantifying luminescence energy produced by the *Photinus pyralis* luciferase-mediated luminescence reaction.

Claim 54 of the '320 patent is directed to a dual-reporter enzyme-mediated luminescence reaction assay kit comprising a first functional enzyme substrate corresponding to a first enzyme-mediated luminescence reaction being assayed, a suitable first container, said first functional enzyme substrate disposed therein, a quench-and-activate composition comprising quench reagents capable of quenching photon emission from the first enzyme-mediated luminescence reaction by a factor of at least 1,000-fold, and a second and distinct functional enzyme substrate corresponding to a second and distinct enzyme-mediated luminescence reaction, a suitable second container, said quench-and-activate composition disposed therein, and instructions for use, wherein said first functional enzyme substrate, and said second and distinct functional enzyme substrate are luciferase substrates, and wherein said quench-and-activate composition comprises one or more quench reagents selected from the group consisting of iodide, iodine, sulfate, nitrate, iso-propanol, (4-aminophenyl)-6-methylbenzothiazole, dimethyldecylphosphine oxide, pyrophosphate, n-butanol, benzothiazole, 2-phenylbenzothiazole, trans-1,2,-diaminocyclohexane-N,N,N',N'-tetraacetic acid, 2-(6'-hydroxy-2'-benzothiazolyl)-thiazole-4-carboxylic acid, ethylenediaminetetraacetic acid, 2(o-hydroxyphenyl)benzothiazole, India fountain pen ink, adenosine 5'-triphosphate 2',3'-acyclic dialcohol, periodate oxidized, borohydride reduced, sodium dodecyl sulfate, citric acid, TweenTM 20, TritonTM X-100, and mixtures thereof; and a second and distinct functional luciferase substrate selected from the group consisting of coelenterate luciferins and functional equivalents thereof, beetle luciferins and functional equivalents thereof, and mixtures thereof.

In contrast, claims 1 and 3 are directed to a method which employs at least one selective quench reagent that quenches a first enzyme-mediated luminescence reaction by at least 35-fold, claim 44 is directed to a kit with at least one functional enzyme substrate for a molecule to be detected by the enzyme-mediated luminescence reaction and a composition comprising at least one selective quench reagent for an anthozoan luciferase in separate containers, claim 49 is directed to a kit with a first functional enzyme substrate for a molecule to be detected by an anthozoan luciferase-mediated luminescence reaction and a quench-and-activate composition comprising at least one selective quench reagent for an anthozoan luciferase-mediated luminescence reaction and a second and distinct functional enzyme substrate corresponding to a second and distinct enzyme-mediated luminescence reaction, and claims 50 and 65 are directed to a kit having a quench-and-activate composition comprising at least one selective quench reagent that is a nonionic detergent that is not Triton® X-100 or Tween® 20, a substrate analog inhibitor for an anthozoan luciferase, or a colored compound.

Moreover, in contrast to claims 44 and 54 in the '320 patent, claim 43 is directed to a kit having at least one functional enzyme substrate for a molecule to be detected by an enzyme-mediated luminescence reaction, wherein the substrate is not a beetle luciferase substrate and a composition comprising at least one selective quench reagent which is a substrate analog inhibitor for the enzyme which mediates the luminescence reaction, a colored compound, or a nonionic detergent which is not Triton® X-100 or Tween® 20, and claims 55-56 and 69 are directed to methods that employ a quench reagent comprising a nonionic detergent that is not Triton® X-100 or Tween® 20, a substrate analog inhibitor for an anthozoan luciferase, a colored compound, or a combination thereof.

Therefore, withdrawal of the nonstatutory obviousness-type double patenting rejections is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of July 2007.

Name

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